

### **REMARKS/ARGUMENTS**

Claims 10-25, directed to methods of preparing a water-dispersible liquid vitamin food additive for animals, are pending in the application. Claims 10-25 stand rejected. Reconsideration of the present application is requested in view of the following remarks.

At page 2 of the Office Action, the Examiner rejected claims 10-25 under 35 USC 103(a) as being unpatentable over Kardys (U.S. Patent No. 3,932,634) in view of Tipton *et al.* (U.S. Patent 5,747,058). The basis for the rejection is that it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to modify the invention of Kardys in view of Tipton *et al.* into the objects of the instant application.

Applicants traverse this rejection. Applicants submit that the present rejection does not establish a *prima facie* case of obviousness with respect to the invention of claims 10-25. As discussed below, both of the references cited by the Examiner relate to different types of compositions and the references, therefore, cannot be combined in the manner suggested by the Examiner. Moreover, there is no suggestion or motivation in either of the references for combining specific teachings relating to viscosity of the formulations. The present rejection represents an impermissible hindsight reconstruction of the invention that uses the Applicant's disclosure as a template for selecting unrelated prior art to construct the claimed methods.

The Kardys patent teaches a vitamin composition for ingestion which consists essentially of 25% to 55% by weight of an oil-soluble vitamin selected from the group consisting of vitamin A, vitamin D<sub>2</sub>, vitamin D<sub>3</sub>, vitamin E or combinations thereof, in water together with a specific dispersing agent which makes up about 50% to about 85% of the total composition. The dispersing agent is a mixture of polyoxyethylene sorbitan monooleate and an ester selected from polyethylene glycol 400 monooleate, decaglycerol dioleate, and decaglycerol tetraoleate. The ratio of the polyoxyethylene sorbitan monooleate to the ester is from about 1:3 to about 3:1 by weight. In order to prepare the compositions, the vitamin is mixed with the dispersing agent. Kardys does not teach

inclusion in the formulation of a C<sub>1</sub> to C<sub>6</sub> alkyl lactate, a component of the water-dispersible liquid vitamin food additive prepared by the claimed methods.

The Tipton *et al.* patent discloses compositions useful for the controlled release of substances wherein the compositions comprise a non-polymeric, non-water soluble high-viscosity liquid carrier material of viscosity of at least 5,000 cP at 37°C that does not crystallize neat under ambient or physiological conditions and a substance to be delivered. Sucrose acetate isobutyrate is exemplified as the high viscosity liquid carrier material. In some embodiments, where the high viscosity of the composition may pose problems for delivery to the site of action, a solvent is added to lower the viscosity of the high viscosity liquid carrier material. Tipton *et al.* in column 2, lines 47-58 and column 5, lines 50-54 discloses a method of preparing such compositions comprising the steps of mixing the high viscosity liquid carrier material with a viscosity lowering water soluble or water miscible solvent to form a lower viscosity liquid carrier material, and mixing the lower viscosity liquid carrier material with the substance to be delivered.

The Tipton *et al.* patent discloses that the lower viscosity composition is easier to place in the body because it flows more easily into and out of syringes or implementation means and can be easily formatted as an emulsion (Col. 5, lines 54-58). On administration, the lower viscosity composition is placed into the body or on a surface, and the solvent dissipates or diffuses away from the composition forming, *in-situ*, a highly viscous implant or composition that releases the substance over time. The compositions are useful for the delivery of substances and for other applications, including the coating of tissue and prevention of adhesions. The substance to be delivered can be a biologically active substance which is defined as an organic molecule (Col. 6, lines 50-65). Vitamins, and in particular vitamins E and C, are disclosed as types of organic molecules in a list that includes proteins, drugs, carbohydrates, genes, lipids and hormones. Ethyl lactate is disclosed as a solvent that can be mixed with the high-viscosity liquid carrier material.

The compositions produced by the methods disclosed in each of the cited references are suitable for different and distinct uses (i.e., for ingestion or for controlled-release of substances). Neither reference teaches that the composition of that reference is

suitable for any other use. Accordingly, Applicant submits that the teachings of the cited references are too different to be combined in the manner suggested by the Examiner.

Even if it were somehow possible to combine the cited references, the Examiner has not established that an artisan of ordinary skill would have been motivated to combine the cited references in the manner suggested in the present Office Action. The recent case, *In re Sang-Su Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed.Cir. 2002), previously submitted to the Examiner in Applicant's response to the Office Action of January 14, 2002, explains the type of explanation and reasoning that is required to establish a *prima facie* case of obviousness and emphasizes that Examiners must clearly explain how and why the teachings of the cited references provide the motivation to combine the references in the manner necessary to support the obviousness rejection. The Federal Circuit has made it very clear that Examiners cannot rely on conclusory statements, such as those used in the present office action, to establish the motivation to combine references.

The motivation for combining the two references provided by the Examiner in the present rejection indicated that one of ordinary skill in the art would seek to resolve the deficiency of the Kardys patent by adding ethyl lactate to the formulation, being motivated to do so as a way of controlling the viscosity of the composition, as well as producing a composition that can be more easily formulated as an emulsion or dispersion, as disclosed by the Tipton *et al.* patent. Additionally, referring to Applicant's previous arguments relating to Tipton *et al.*, the Examiner indicated that it is not necessary that the art recognize each and every function of a component to be included within a composition, only that a particular component is known as being useful in a particular composition.

Applicants submit, however, that the cited references do not provide motivation for combining their teachings in the manner suggested by the Examiner. The formulation disclosed in Kardys rapidly disperses in water (Col. 2, lines 4-5), and there is no mention in the patent of a need to control viscosity of the formulation. One skilled in the art would have no reason or incentive to add ethyl lactate to the Kardys formulation or the method of preparing such formulation to solve the problem of controlling viscosity as

asserted by the Examiner when such a problem with the Kardys formulation was not disclosed or suggested in the reference itself.

The deficiencies of the Kardys reference are not overcome by the addition of Tipton *et al.* Tipton *et al.* neither discloses nor suggests controlling viscosity of a vitamin formulation of the type disclosed in Kardys. Tipton *et al.* is concerned with a composition for controlled release of a biologically active substance wherein the composition contains a non-polymeric non-water soluble high viscosity liquid carrier material and methods of preparing such compositions. The Examiner pointed out portions of Tipton *et al.* that refer to lowering the viscosity of the composition, col. 5, lines 50-57 and column 10, lines 15-16, but these portions of Tipton *et al.* fall far short of providing motivation to combine the teachings of the cited references. Column 5, lines 50-57 of Tipton *et al.* discloses mixing the high viscosity liquid carrier material with a viscosity lowering water soluble or water miscible solvent to form a lower viscosity liquid carrier material and then mixing the lower viscosity liquid carrier material with a substrate for controlled delivery. Column 10, lines 15-16 recite examples of suitable solvents, including ethyl lactate. There is no suggestion or disclosure in Tipton *et al.* that a solvent such as ethyl lactate could or should be used to control the viscosity of a formulation that does not contain a high viscosity liquid carrier material, let alone a vitamin formulation as disclosed in Kardys.

To simply point to portions of the cited references that teach certain elements of the claimed invention and then state that the combination of all of these elements would be obvious to obtain a formulation having the properties that are described in the present application is a classic example of hindsight reconstruction and is improper. The teachings of the present invention regarding the desired properties of the formulation produced by the claimed methods cannot be used as part of the basis for an obviousness rejection. The cited references, by themselves, must teach or suggest the claimed invention and provide the motivation to combine the references in the manner necessary to produce the claimed invention. In the present rejection, the Examiner has not only failed to explain why or how the teachings of the references can be combined, the Examiner has also failed to explain how the teachings of the references, by themselves, would motivate an artisan to combine the teachings in a manner which would produce the

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presently claimed invention. Accordingly, it is respectfully submitted that the Examiner has not established a *prima facie* case of obviousness. Claims 10-25 are therefore not obvious over Kardys in view of Tipton *et al.* Withdrawal of this section 103 rejection is requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

Respectfully submitted,

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